I/S: A JOURNAL OF LAW AND POLICY FOR THE INFORMATION SOCIETY

Privacy Implications of Mandatory Immunizations, Exemptions, and Immunization Information Systems

KYLA L. KELCH*

Abstract: The creation of digital immunization information systems is part of the national movement to digitize healthcare records. While there are several benefits to the digitization of healthcare information, including the ease and accessibility with which this information can be accessed, there are also privacy objections to this form of record keeping. Immunization information systems, which store information regarding immunizations, are further objectionable to some based on opposition to immunizations themselves. This note will explore, from a privacy standpoint, the history of immunizations in America, as well as the objections and benefits to both immunizations and the electronic storage of immunization information.

* Kyla Kelch is a Juris Doctor candidate at The Ohio State University Moritz College of Law, Class of 2009. She earned a Master's of Education degree from The Ohio State University in 2004, and a Bachelor of Arts degree, *with Honors* in the Liberal Arts and *Distinction* in English, from The Ohio State University in 2003. The author has also earned designation as a Certified Information Privacy Professional by the International Association of Privacy Professionals.

I. INTRODUCTION

Recent developments in American healthcare will inevitably impact the future of healthcare privacy regulation in a number of ways. First, the digitization of medical and personal health records is becoming increasingly prevalent. Insurance companies, healthcare providers, and government entities tout electronic storage systems for health records and the electronic systems that make it possible to exchange the information, as positive technological developments with both societal and economic benefits. In addition, the White House mandates the implementation of universal electronic health records for all Americans by 2014.[1]

Second, the shift to electronic health records has led to the development of immunization information systems ("IIS") (electronic databases) to store and exchange immunization information. Most states have already implemented IIS. In reflecting on the privacy implications of mandated IIS, it is also important to consider recent changes in public perception regarding the necessity and safety of immunizations. Many parents have historically objected to vaccinations based on religious or philosophical convictions. More recently, however, concentrated "pockets of vaccine rejection"—communities with high percentages of unvaccinated children—are on the rise as a result of what experts refer to as "a false sense of cause and effect."[2] Because autism tends to emerge at the same age that children receive vaccinations, parents assume that vaccinations are the culprit. Presumably as a result of this false sense of cause and effect, public health officials have found concentrated areas of "exemptors," from ten to nineteen percent, in "affluent, progressive communities" like Ashland, Oregon; Vashon Island, Washington; and some counties in California.[3] The result of these isolated pockets of unvaccinated children is alarming. By summer's end, 2008, "federal officials reported that measles cases in the United States have reached

---

[1] Lucy L. Thomson, *Transforming Healthcare with Information Technology*, THE PRIVACY ADVISOR (Int'l Ass'n. of Privacy Prof., York, Me.), June 2008, at 9.

[2] Deborah L. Shelton & Deanese Williams-Harris, *Kids' Vaccinations Face Risky Resistance*, CHICAGOTRIBUNE.COM, Aug. 26, 2008, http://www.chicagotribune.com/features/lifestyle/health/chi-vaccine-suspicion_26aug26,0,7718636.story.

[3] *Id.*

their highest level in more than a decade, with nearly half of the cases involving children of parents who opted against vaccination."[4]

Certainly, the introduction of electronic immunization storage technology, coupled with the increasing prevalence of communities of parents who opt-out of immunizations for their children,[5] has led some privacy experts to note the potential for change in privacy regulation. This note discusses mandatory vaccinations, exemptions, and vaccine registries and considers the implications of two main types of privacy issues: decisional privacy and information privacy.

II. AN OVERVIEW OF IMMUNIZATIONS AND IIS IN THE UNITED STATES

The United States mandates vaccinations for children entering school in order to create "herd immunity"[6] and eliminate the spread of dangerous or easily preventable diseases. These procedures have long been the norm, but have always been subject to some objection. The issue presents interesting privacy questions from personal, public, and professional perspectives. For example, arguments have been advanced suggesting that mandatory vaccination laws impinge on the autonomy and familial privacy of parents and children, and also undermine private religious beliefs and personal convictions.[7]

Further, from a privacy perspective, the ever-growing prevalence of IIS garners both avid support and avid opposition. To date, most states [8] have instituted IIS, which allow disclosure of "specified information regarding patients' medical records to the State

---

[4] *Id.*

[5] Lisa Farino, *The Risks of Skipping Kids' Vaccines*, MSN HEALTH & FITNESS, http://health.msn.com/health-topics/vaccination-guide.aspx (last visited Jan. 1, 2009).

[6] Herd immunity protects a small number of unvaccinated individuals within a large group when a significant portion of the group members are immune to a disease. *See* Donya Khalili & Arthur Caplan, *Off the Grid: Vaccinations Among Homeschooled Children*, 35 J.L. MED. & ETHICS 471, 473 (2007).

[7] Steve P. Calandrillo, *Vanishing Vaccinations: Why are so Many Americans Opting out of Vaccinating Their Children?* 37 U. MICH. J.L. REFORM 353, 394 (2004).

[8] As of 2007, only Massachusetts, New Hampshire, Kentucky, and Hawaii did not have IIS in place. Dep't of Health and Hum. Servs., Ctrs. For Disease Control and Prevention, 2007 Child Participation Map, http://www.cdc.gov/vaccines/programs/iis/rates/2007-child-map.htm (last visited Feb. 3, 2009).

Department of Health Services and local health departments."[9] These disclosure systems, also known as "vaccine registries," attempt to collect immunization information about children within a specific geographic locality and generally require some degree of recordation of children's identifying information and immunization histories.[10] Money-saving record consolidation and the ability of IIS to generate reminder notices for children when vaccinations come due are just some of the benefits of the system.[11] The Department of Health and Human Services, Centers for Disease Control and Prevention has identified several other categories of benefits IIS provide.[12]

The government has additionally recognized that IIS have the potential to add to public health by helping to ensure that the vast majority of the population receives vaccinations. In 1993, then-President Bill Clinton sent to Congress the Comprehensive Child Immunization Act of 1993, [13] which included the proposed establishment of a "national immunization tracking system."[14] Since

---

[9] Kelly L. McDole, *Health and Welfare; Disclosure of Immunization Information*, 27 PAC. L.J. 832, 832 (1996). *See also* Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, 2007 Child Participation Map, http://www.cdc.gov/vaccines/programs/iis/rates/2007-child-map.htm (last visited Feb. 3, 2009).

[10] Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, IIS: Frequently Asked Questions, http://www.cdc.gov/vaccines/programs/iis/faq.htm [hereinafter IIS: FAQs] (last visited Jan. 1, 2009).

[11] *Id.*

[12] Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, What is IIS?, http://www.cdc.gov/vaccines/programs/iis/what-iis.htm (last visited Nov. 3, 2008). First, IIS help identify at-risk populations who could greatly benefit from vaccinations and maximize resources to service these populations. *See id.* IIS also consolidate records, combining immunization records from various sources to create one official immunization record. *See id.* IIS are able to generate reminders for immunization due dates and ensure that children "get only the vaccinations they need." *Id.* Data exchange is also a benefit of IIS, allowing immunization healthcare providers to "work more efficiently." *Id.* Privacy and confidentiality are also addressed by the Centers for Disease Control and Prevention, which require all IIS to have a written privacy policy clearly defining notification, choice regarding participation, use of IIS information, access to and disclosure of IIS information, and the time period of data retention. *See id.*

[13] Press Release, Office of the Press Sec'y, The White House, Comprehensive Child Immunization Act of 1993 (Apr. 1, 1993), *available at* http://www.ibiblio.org/pub/archives/whitehouse-papers/1993/Apr/Child-Immunization-Act-of-1993-40193.

[14] *Id.*

this proposal was made, tracking systems have been established in forty-eight states, and the American Immunization Registry Association was established in 1999 to "advocate for [IIS] development and sustainability."[15] Further, in July 2001, the National Center for Immunization and Respiratory Disease developed a plan to reach the 2010 immunization registry national objective, which would increase the proportion of children under the age of six who participate in fully operational IIS to 95%.[16]

Those in opposition to IIS, however, believe that any societal benefits are counteracted by the privacy invasion such registries require.[17] Objections to IIS include the worry that children's identifying information will not be adequately protected and that the information will be used to negatively target certain populations. Prior to IIS, insurance companies, schools, and the government did not have ready access to vaccination records; with IIS that will no longer be the case. With the mandatory implementation of IIS, there is the potential that such entities could negatively penalize parents who choose not to have their children vaccinated for religious, medical, or philosophical reasons.

Perhaps in part because of some of these objections, many states have carved out exemptions to the mandatory vaccination laws. In addition, many state statutes governing IIS provide opt-out provisions or require informed consent. As one might suspect, exemptions and opt-out provisions are subject to much criticism as well. Critics argue that exemptions to mandatory immunizations undermine societal health, subject children to the will of their parents, thus reducing or eliminating their own autonomy and privacy, and in some cases, undermine religious privacy by favoring only those who belong to established religions that oppose vaccination.[18] However, proponents

---

[15] AM. IMMUNIZATION REGISTRY ASS'N, STRATEGIC PLAN 2007–2010, http://www.immregistries.org/pdf/STRATEGICPLANDOCUMENT07.pdf (last visited Jan. 1, 2009).

[16] DEP'T OF HEALTH & HUM. SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, IMMUNIZATION REGISTRY STRATEGIC PLAN 2002–2007 (2003), http://www.cdc.gov/vaccines/programs/iis/activities/downloads/strat-plan.pdf. Currently, 24% of children are participating in IIS. *Id.* at 3.

[17] Charity Scott, *Is Too Much Privacy Bad for Your Health? An Introduction to the Law, Ethics, and HIPAA Rule on Medical Privacy*, 17 GA. ST. U. L. REV. 481, 496 (2000).

[18] Alicia Novak, *The Religious and Philosophical Exemptions to State-Compelled Vaccination: Constitutional and Other Challenges*, 7 U. PA. J. CONST. L. 1101, 1103 (2004–2005).

of mandatory vaccinations argue that the potential for the effective handling of public health emergencies far outweighs any privacy concerns raised by IIS.

While there are additional arguments advanced on each side, it is worth looking at these arguments from a privacy perspective to determine if there is, in fact, a solution or approach to this debate that can address the concerns advanced on both sides.

III. CONSTITUTIONAL PRIVACY

The Supreme Court has decided that parents do have some privacy rights to "direct their children's upbringing free from governmental intrusion."[19] However, in *Prince v. Massachusetts*,[20] the Supreme Court identified limitations on this right, holding that parents' rights must be balanced against the state's interest in protecting children's health, education, safety, and well being.[21] Supporters of exemptions to mandatory vaccination have expressed concern about where the Court's holding leaves the constitutional protection of parental autonomy.[22] There are also concerns that too much government intrusion into matters of the home will backfire. The tension arises in balancing individual freedom and parental autonomy with the health of society as a whole.[23] Parents seem to opt their children out of vaccinations for two main reasons. For many, religious beliefs preclude vaccination, while others claim exemption due to fear that vaccinations will have an adverse effect on their children's health. Imposing vaccination on these types of families would not only undermine religious freedom, but obviously undermine parental autonomy as well.

Despite the fear of public outcry, the legal history of vaccination litigation demonstrates that, in most cases, mandatory vaccination law is not subordinate to personal autonomy and decisional privacy. For example, in 1905, the Supreme Court decided *Jacobson v.*

---

[19] Khalili & Caplan, *supra* note 6, at 471.

[20] 321 U.S. 158 (1944).

[21] Khalili & Caplan, *supra* note 6, at 471.

[22] *Id.*

[23] *See* Melinda Wharton et al., *Childhood Immunization: Exemptions and Vaccine Safety*, 33:4 J. L. MED. & ETHICS 34, 34 (2005).

Massachusetts,[24] holding that a regulation mandating smallpox vaccination was a "reasonable exercise of a state's police power and did not violate an individual's fundamental liberty rights under the Fourteenth Amendment of the Constitution."[25] Just over a decade later, the Court ruled in *Zucht v. King* that schools may constitutionally require children to present proof of vaccination prior to attendance; failure to do so would exclude the child from school.[26]

The Supreme Court's rulings in these cases create obvious infringements on parental privacy and autonomy. However, the parent's autonomy may not be the only kind of autonomy at stake. While many advance the argument that mandatory vaccination laws violate a parent's right to raise his or her child without government intrusion, it is also important to consider the autonomy of the child: "[E]xemption statutes should be eliminated or severely restricted because they make martyrs of young unvaccinated children who cannot decide for themselves if they wish to avoid the illnesses targeted by the vaccinations that they do not receive."[27] As the Supreme Court in *Prince v. Massachusetts* explained: "Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."[28]

Another view of the child's autonomy was put forth in a 1979 Mississippi Supreme Court decision and is evidenced in that state's law, which provides no religious or philosophical exemptions from mandatory vaccination. The Mississippi Supreme Court decided that "[e]xcluding certain children from the requirements solely based on their parent's religious beliefs forces immunized children to bear the burden of keeping overall protection levels high and increase their risk of disease exposure through association with unvaccinated children."[29] The Mississippi court seems to have focused on the fact

---

[24] 197 U.S. 11 (1905).

[25] *Id.* at 35 (quoting Linda E. LeFever, *Religious Exemptions from School Immunization: A Sincere Belief or a Legal Loophole?*, 110 PENN ST. L. REV. 1047, 1051 (2006)).

[26] 260 U.S. 174 (1922). *See also* LeFever, *supra* note 25, at 1051.

[27] Novak, *supra* note 18, at 1118.

[28] Prince v. Massachusetts, 321 U.S. 158, 170 (1944).

[29] *See* Brown v. Stone, 378 So. 2d 218 (Miss. 1979) (quoting LeFever, *supra* note 25, at 1064).

that the exemption is the parents' decision, and therefore does not necessarily have a bearing on the child's autonomy, and further, the children who are immunized deserve protection paramount to individual autonomy.

IV. BENEFITS OF MANDATORY VACCINATION AND IMMUNIZATION INFORMATION SYSTEMS; SOCIETAL GOOD

Immunizations are mandated not to protect individual citizens, but to "protect the health of the community as a whole."[30] A group as a whole is better able to resist attack when a significant proportion of its members are immune to a disease. This is called "herd immunity;" it protects a "small number of unvaccinated individuals in a community from coming into contact with the disease because of the vaccination of their neighbors."[31] The proportion of a community that must be vaccinated for herd immunity to develop varies by disease, but is usually somewhere around 90% for most childhood vaccines.[32]

It is difficult to argue against the proposition that mandatory vaccinations are beneficial to society as a whole. Since the 1900s, the average lifespan of U.S. residents has increased by more than thirty years.[33] Twenty-five years of that increase can be attributed "to advances in public health, most prominently, vaccination."[34] This is an incredible increase in longevity. The non-existence of certain diseases today is so taken for granted that it is difficult to imagine a time when people regularly died at young ages from smallpox, polio, or measles.

However, "[a]s more and more people choose not to vaccinate, they undermine the herd immunity that protects those who cannot be vaccinated for medical reasons, putting the community's health at risk."[35] If the number of people choosing to forgo vaccination continues to increase at rates that leave over 10% of the population unprotected, some of the diseases eradicated long ago may stage a

---

[30] Khalili & Caplan, *supra* note 6, at 473.

[31] *Id.*

[32] *Id.*

[33] Novak, *supra* note 18, at 1105–06.

[34] *Id.*

[35] Khalili & Caplan, *supra* note 6, at 473.

comeback. Parents who choose not to immunize their children are "extracting the benefit" from other parents who have vaccinated their children.[36] "This 'free rider' problem takes advantage" of those who have placed civic responsibility ahead of family interest.[37] To further this point, "unvaccinated children increase the risk of disease exposure and transmission to the national community by causing a decline in the overall immunization levels in the United States."[38] Accordingly, it is beneficial to societal health when the vast majority of the population undergoes vaccination.[39]

Immunization information systems add to the public health benefits provided by mandatory vaccination in a number of ways. Population-based data through IIS can contribute to the identification of incidence and patterns of disease, thereby improving public health.[40] "Tracking of health risks allows those concerned with public health to concentrate resources and focus interventions in areas of greatest need."[41] Healthcare providers and health departments also obtain an advantage from access to registries containing immunization information. They are able to understand more fully

---

[36] *Id.* at 474 (quoting Douglas S. Diekama, *Responding to Parental Refusals to Immunization of Children*, 115 PEDIATRICS 1428, 1429 (May 2005)).

[37] *Id.*

[38] LeFever, *supra* note 25, at 1048.

[39] An additional societal benefit of mandatory vaccination implicates a cost benefit analysis. To this point, vaccinations, when large-scale, save resources. *See* Calandrillo, *supra* note 7, at 379. "Vaccine preventable diseases cost sixteen times more in medical related costs than do the vaccines that prevent those diseases." *Id.* at 380. "American adults contracting vaccine preventable diseases still result in ten billion dollars worth of unnecessary healthcare costs [each year]." *Id.* at 381. Therefore, vaccinations can save Americans time, energy, effort, and resources. In addition to the intangible losses produced by forgoing vaccination, this choice results in 30,000 otherwise avoidable deaths in the United States each year. *Id.* at 381. In sum, mandatory vaccinations have wide spread societal benefits, preventing death, disease, and the waste of important resources. To be fair, it should be noted that anti-vaccination advocate Patty Smith contends that "[t]he issue of the costs and benefits of mass vaccination is not examined objectively. What results instead is a cover-up of unpleasant truths." Patty Smith, *Public Interest or Public Menace? The Truth Behind Vaccines*, ALIVE: CANADIAN J. OF HEALTH & NUTRITION, Sept. 2005, at 50.

[40] Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 482 (1995).

[41] *Id.* at 483.

"the determinants of disease . . . and outcomes following interventions."[42]

In particular, doctors such as Dr. Robert Daum, director of the pediatric immunization program at the University of Chicago Hospitals, look to IIS for help with inner-city or low-income patients because of the sheer number of clinics they have visited and the number of records that must be consolidated.[43] Parents, especially those who are economically disadvantaged, may have difficulty keeping up with the recommended immunization schedule. The 2008 vaccination schedule for children, as recommended by the Center for Disease Control, is complex and includes over ten different types of vaccinations, each with a series of doses that must be administered at various intervals, some beginning at birth and others ranging up to six years of age.[44] One can imagine the organizational and economic benefits, not to mention the health benefits, of IIS for parents and children who do not have a regular pediatrician, but visit a number of healthcare providers. In addition, the majority of parents entering an emergency room situation, regardless of income level, do not know the status of their children's vaccinations, and very few parents can "correctly recall[] the immunizations their children received."[45] IIS can help to efficiently provide information to doctors and healthcare providers in just these types of critical situations.

One recent example of a practical success of IIS involves the use of such a system after the occurrence of Hurricane Katrina in 2005.[46] The Louisiana Immunization Network for Kids Statewide ultimately saved an estimated $4.6 million in revaccination and related fees because a backup system preserved immunization information

---

[42] *Id.*

[43] Frank James, *Children's Vaccine Registry Raises Medical Privacy Fears*, WASH. BUREAU, May 17, 1999, http://www.compleatmother.com/registry.htm.

[44] DEP'T OF HEALTH AND HUM. SERVS., CTRS. FOR DISEASE CONTROL AND PREVENTION, RECOMMENDED IMMUNIZATION SCHEDULE FOR PERSONS AGED 0–6 YEARS (2008), http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2008/08_0-6yrs_schedule_pss.pdf.

[45] James, *supra* note 43.

[46] Julie A. Boom et al., *The Success of an Immunization Information System in the Wake of Hurricane Katrina*, 119 PEDIATRICS 1213 (2007), *available at* http://pediatrics.aappublications.org/cgi/content/abstract/119/6/1213.

following the hurricane.[47] The savings were the result of the recovery of over 21,000 immunization records for children who were forced to evacuate because of the hurricane.[48] Healthcare providers caring for displaced persons were able to access records of immunization history data and avoid the waste of resources and the unnecessary revaccination of children.[49] Supporters of IIS cite the example of its use after Hurricane Katrina as a model of the beneficial use of IIS for "future disaster-preparedness planning."[50]

Clearly, IIS use will continue to grow and improve. However, many object to the use of such systems for privacy reasons. These objections will be further discussed below.

V. IMMUNIZATION LAW AND RELIGIOUS EXEMPTIONS

It is additionally necessary to examine the structure of state statutes concerning immunizations and to explore the effects of the varying laws on the immunization debate. Under Ohio Revised Code section 3313.67, for example:

> [T]he board of education of each city, exempted village, or local school district may make and enforce such rules to secure the immunization of, and to prevent the spread of communicable diseases among the pupils attending or eligible to attend the schools of the district, as in its opinion the safety and interest of the public require.[51]

The Ohio statute additionally includes a broad exemption. Section 3313.671 of Ohio Revised Code states: "A pupil who presents a written statement of the pupil's parent or guardian in which the parent or guardian declines to have the pupil immunized for reasons of

---

[47] Gary A. Urquhart et al., *Immunization Information Systems Use During a Public Health Emergency in the United States*, 13 J. OF PUB. HEALTH MGMT. & PRACTICE 481 (2007), *available at* http://www.jphmp.com/pt/re/jphmp/abstract.00124784-200709000-00009.htm.

[48] *Id.*

[49] *Id.*

[50] Boom et al., *supra* note 46, at 1213–17.

[51] OHIO REV. CODE ANN. § 3313.67 (2005).

conscience, including religious convictions, is not required to be immunized."[52] This seems to suggest that any objection, whether religiously based or for "reasons of conscience," will exempt the student from immunization.

Twenty states have exemptions similar to the Ohio statute, permitting exemptions for religious belief or philosophical reasons.[53] Twenty-eight states allow for a religious exemption only[54] and four states require the religion to be organized, recognized or established.[55] Only Mississippi and West Virginia do not permit parents to claim either exemption.[56] Fourteen states require "genuinely and sincerely held religious beliefs," while twenty-eight states only require an "affidavit or form stating opposition to vaccination based on religious grounds."[57]

The very structure of the varying exemptions or non-exemptions presents a number of issues. For example, statutes that limit the use of the religious exemption to adherents of "organized religion" necessarily exclude many parents who hold personal or religious convictions but do not belong to an organized religion. Further, the statutes that only allow exemptions for "genuine" religious beliefs leave the interpretation of "genuine" up for debate. Many object to the statutorily mandated intrusion into privately held religious or philosophical beliefs in order to obtain immunization exemptions.

In particular, religious sects such as Christian Scientists and the Amish are opposed to vaccinations across the board. Other parents with religious objections oppose only those vaccines created using aborted fetal tissue research.[58] In particular, Shannon Law, a Catholic parent, filed suit to exempt her children from the varicella vaccine because "the vaccine is derived from the stem cell lines of aborted fetuses."[59] As a Catholic, Law argued, she was religiously and morally

---

[52] OHIO REV. CODE ANN. § 3313.671 (2005).

[53] LeFever, *supra* note 25, at 1052.

[54] *Id.*

[55] Wharton et al., *supra* note 23, at 36.

[56] LeFever, *supra* note 25, at 1053.

[57] Wharton et al., *supra* note 23, at 34.

[58] Sean Coletti, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1357 (2004).

[59] *Id.*

opposed to abortion. Therefore, she could not condone the use of this particular vaccination on her children.[60] The ability of parents to use exemptions may preserve their ability to stand by their private religious convictions, whether they are religiously opposed to all vaccinations or only specific ones.[61]

Many argue that the protection of religious freedom and privacy should not counter-balance the need to protect public health. By absolving individuals with religious objections from immunization requirements, the burden to protect the community from disease shifts solely to the non-religious.[62] Further, when large populations of religious sects fail to vaccinate children, the potential for outbreaks among specific communities arises alongside the potential for the spread of disease to other populations.[63] For example, the last two polio outbreaks in America occurred within Amish, Mennonite, and Christian Science communities.[64] Many believe the potential for the spread of disease does not justify preservation of religious privacies.

VI. NON-RELIGIOUS EXEMPTIONS

Every state exempts children who are advised for medical reasons against vaccination, such as children with compromised immune systems.[65] However, there are inherent medical risks to all vaccines.[66]

---

[60] *Id.*

[61] The religious aspect of exemptions also necessarily implicates both the Free Exercise Clause and the Establishment Clause of the First Amendment. The problem lies in the tension these two provisions have with one another. For example, if a state allows an exemption to an immunization law for religious reasons, it might be viewed as endorsing religion in violation of the Establishment Clause. However, failure to recognize or allow a religious exemption potentially infringes on the right to free exercise of religion.

[62] LeFever, *supra* note 25, at 1062.

[63] The Amish and Christian Scientists, for example, are fundamentally opposed to vaccinations. Khalili & Caplan, *supra* note 6, at 472.

[64] *Id.*

[65] LeFever, *supra* note 25, at 1052.

[66] "The great majority of side effects are local and minor, such as pain . . . inflammation and swelling at the injection site. These mild complications may occur in up to 50% of vaccines given." Calandrillo, *supra* note 7, at 389. In addition to mild potential complications that all vaccinations present, "[s]ystemic symptoms specific to each particular vaccine may also occur, including fever, headache, irritability, vomiting, diminished activity and other complications." *Id.* at 390.

Arguably, even the potential for slight risks should justify parents in exempting their children from vaccination. Parents have an interest in protecting their children from pain and suffering, and the exemption option may provide for this protection by allowing parents the decisional privacy to make choices regarding their children's health.

Acknowledging that more serious risks such as allergic reactions, deafness, or brain damage are slight, but exist nonetheless, Congress enacted the National Childhood Vaccine Injury Act[67] to compensate children injured by vaccines.[68] Some parents may decide that despite the minimal risk of these problems actually affecting their children, they would rather take advantage of an exemption than risk having to be compensated by the Vaccine Injury Act.

An additional perceived benefit of claiming a medical exemption is the ability of exempted children to avoid altogether the debate surrounding whether the thimerosal contained in some vaccines causes autism.[69] Many have recently raised concerns that the preservative thimerosal, which was used in many vaccinations and contained ethyl mercury, "causes not only allergies but autism as well."[70] Other allegations have been advanced pointing to a link between thimerosal and other serious conditions like multiple sclerosis, sudden infant death syndrome, diabetes, asthma, and

---

[67] 42 U.S.C. §§ 300aa-1 to aa-34 (2008).

[68] Calandrillo, *supra* note 7, at 390.

[69] Credible advocates still exist on both sides of the debate. Dr. Moskowitz contends that his thirty-five years of medical practice have shown that "all vaccines carry an important risk of chronic disease . . . and [is] indeed central to how they work." Richard Moskowitz, *Hidden in Plain Sight: The Role of Vaccines in Chronic Disease*, 98 AM. J. OF HOMEOPATHIC MED. 15, 15 (2005). Dr. Moskowitz feels that any concerns expressed by legislators, parents, or the media are too readily dismissed and are further "automatic[ally] deni[ed] by medical and public health authorities alike." *Id.* On the other hand, *Health* magazine published a 2004 article noting that "many studies have been completed since the link was first proposed, and their results are reassuring." Kathleen M. Wong, *Do Vaccines Cause Autism? Scientists Who Look at the Question in Different Ways Come up with the Same Answer*, HEALTH, June 2004, at 133. Wong's article suggests that the connection is not a connection at all, but a coincidence: "Affected children simply receive the vaccine around the time their disorder is recognized." *Id.* The article further makes mention of a Danish study which found that "unvaccinated children were just as likely to be diagnosed with autism as those who had gotten the shots." *Id.* Based on the continued debate surrounding autism, many parents may err on the side of caution and find refuge in an exemption.

[70] Calandrillo, *supra* note 7, at 390.

bacterial infection.[71] None of these risks have ever been conclusively proven, and parents may no longer be able to rely on the argument that thimerosal is the culprit, because "thimerosal has been removed from all routinely-given vaccines to prevent any further potential risk."[72] Of course, "[i]f thimerosal was indeed the root of vaccine-related injury in the past few decades, then one would expect its removal would lead directly and quickly to a stunning decline in autism cases."[73] However, contrary to those expectations, it does not appear that the instances of autism have dropped over the last few years.[74]

It is likely that parents and other proponents of the exemptions will continue to argue that chemicals in the make-up of vaccinations might pose serious health threats, but studies have shown that "receiv[ing] vaccinations is approximately one thousand times safer than running the chance of contracting the disease itself in order to avoid an adverse immunization event."[75] While the odds are good, some parents may feel that they do not want to gamble where their children's livelihoods are at stake. These parents want to reserve the right to make private decisions concerning their children's health without government intrusion.

VII. OBJECTIONS TO IIS BASED ON PERCEIVED PRIVACY VIOLATIONS

The personal information contained in an IIS must at least include the patient's full name; the patient's date of birth, sex, and birth state and country; the patient's mother's name; and the types and dates of vaccines received.[76] For some anti-registry advocates, even this minimum amount of information is too invasive, given the potential for misuse or unauthorized disclosure. In addition, while the Centers for Disease Control Prevention website assures that "state law requires that information in IIS be kept confidential," and that parents can "opt-out" of the registry by contacting their specific state IIS

---

[71] *Id* at 390–91.

[72] *Id.* at 391.

[73] *Id.* at 400.

[74] *Id.*

[75] *Id* at 391.

[76] However, IIS information may vary by state. IIS: FAQs, *supra* note 10.

administrator, contradicting information is contained within the same website. [77] According to the Centers for Disease Control and Prevention's, *National Immunization Program Survey of State Immunization Information System Legislation*, of the thirteen states that mandate IIS reporting, only seven give notice to parents of their children's inclusion in the IIS, and twelve of the thirteen only require implied consent.[78] Even more troubling is that of the twelve states requiring implied consent, five states do not have legislation that includes provisions to opt-out or limit access.[79]

Further, the Centers for Disease Control and Prevention website, concurrent with providing assurances to parents that confidentiality and privacy will be maintained, encourages healthcare provider participation in IIS by confirming that statutory provisions provide "immunities from civil and/or criminal liability for providers who make good faith disclosures to immunization registries or rely on information in immunization registries."[80] These types of provisions, while assuaging the concerns of healthcare providers, add to the fears harbored by some parents; they may fear that providers will not be particularly concerned with privacy, because any disclosure will be easily justifiable under a "good faith" standard– a standard that provides little deterrence.

Barbara Loe Fisher, co-founder and President of the National Vaccine Information Center, purported to represent the views of "tens of thousands of citizens from every state in America" at the 1998 Immunization Registries Workgroup on Privacy and Confidentiality.[81] Specifically, Fisher explained that Americans are predominantly opposed to "being forced, without their informed consent, to use every vaccine the drug companies produce and public health officials decide

---

[77] *Id.*

[78] Ctrs. for Disease Control and Prevention, National Immunization Program Survey of State Immunization Information System Legislation [hereinafter Nat'l IIS Survey], http://www.cdc.gov/vaccines/programs/iis/privacy/legsurv.htm (last modified Nov. 9, 2005).

[79] *Id.* Clearly, this is in direct odds with the website's assurance under the "Frequently Asked Questions" section that parents can "opt-out." *Id.*

[80] IIS: FAQs, *supra* note 10.

[81] Barbara Loe Fisher, President, Nat'l Vaccine Info. Ctr., Statement to the Nat'l Vaccine Advisory Comm. Immunization Registries Workgroup on Privacy and Confidentiality (May 14, 1998), *available at* http://909shot.com/Loe_Fisher/blf51498tracking.htm.

to mandate."[82] Anti-vaccine registry advocates also claim that the decision to implement vaccine registries was made "behind closed doors" by special interest groups, pharmaceutical companies, and government health agencies. [83] Opponents claim that vaccine registries are unwarranted because traditional public health measures have achieved a 98% vaccination rate. [84] Further, "state vaccine tracking registries [promoted] in the name of protecting the public health are simply a smokescreen for the creation of a government-operated system that will further invade . . . privacy and take away endangered liberties."[85]

Those who oppose registries believe that IIS will make health records and personal details of movement from state to state available to the government, drug companies, and insurance company employees.[86] Those critics are of the opinion that these types of information should only be available to personal physicians.[87] The initial draft of the "citizen's petition" proposed by the privacy work-group identified the would-be national vaccine tracking system as a "fundamental violation of privacy and civil liberties."[88] In response to this criticism, the petition included provisions calling for prior written consent to enroll any child in a vaccine tracking system.[89] Further, the petition expressed concern that a national system could be used to discriminate against and punish parents who do not conform to government recommended healthcare policies.[90]

One of the main objections of registry critics is that registries will be expanded to encompass more than just vaccination information and may one day allow the government to access all of a citizen's

---

[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

private health information.[91] A common label for IIS among registry critics is "big brother;" references have even been made likening registries to communist policies of other countries.[92]

VIII. THE HIPAA PRIVACY RULE AND IIS

While the Health Insurance Portability and Accountability Act ("HIPAA")[93] Privacy Rule[94] currently governs use and disclosure of protected health information, it generally provides no protection for information contained within IIS.[95] Specifically, section 164.512(b) of the rule permits covered entities to disclose protected health information when the entity collecting or receiving the information is a public health authority legally authorized to collect such information for purposes such as preventing and controlling disease.[96] For IIS, this means that covered entities may disclose protected health information to registries without providing notice to, or requiring the consent, of parents. [97] Further, the rule does not prevent IIS administrators from re-disclosing immunization information, unless an individual state law directly governs.[98]

There are several specific exceptions to the HIPAA Privacy Rule that allow immunization information to be submitted by healthcare

---

[91] James, *supra* note 43.

[92] *Id. See also Big Brother is Monitoring Us by Databases*, 32 THE PHYLLIS SCHLAFLY REPORT (Eagle Forum, Alton, Ill.), Sept. 1998, *available at* http://www.eagleforum.org/psr/1998/sept98/psrsept98.html.

[93] Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1936 (1996).

[94] 45 C.F.R. § 164.512 (2008).

[95] *See* MINNESOTA DEPT. OF HEALTH, DISCLOSURE TO PUBLIC HEALTH UNDER THE HIPAA PRIVACY RULE (2006), http://www.health.state.mn.us/divs/idepc/immunize/registry/hipaa.pdf. If a registry happened to be a covered entity itself, then HIPAA could apply. State public health agencies, however, are not covered entities unless they qualify as a covered entity due to the manner in which they receive electronic payments under HIPAA. *Id.*

[96] *Id.*

[97] *Id.*

[98] *Id.*

providers to registries.[99] Section 164.512(a) allows an exception for covered entities to disclose protected health information if the use or disclosure is required by law.[100] Examples of health information that must be reported by law include the reporting of certain diseases that are highly contagious and the reporting of injuries resulting from domestic or child abuse.[101] An exception is also permitted for protected information used or disclosed for public health activities under section 164.512(b).[102] These types of public health activities include gathering statistics that a public health authority may use to prevent or control disease, like birth and death statistics and public health investigations or interventions.[103] The third exception allows use and disclosure of protected information for health oversight activities necessary for supervision of the healthcare system or compliance with civil rights laws under section 164.512(d).[104] Lastly, an exception is provided for protected information used or disclosed to avert a serious threat to health of safety under section 164.512(j).[105] This exception allows good faith disclosure necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.[106]

IX. SOLUTIONS TO THE IMMUNIZATION/EXEMPTION DEBATE

Recent studies show a surprising trend in the types of parents who are exempting their children from vaccination. These parents tend to be highly educated, with high annual incomes.[107] This trend is

---

[99] TEXAS DEPT. OF ST. HEALTH SERVS., IMPACT OF HIPAA ON REPORTING TO THE TEXAS IMMUNIZATION REGISTRY (2005), http://www.dshs.state.tx.us/immunize/docs/Payors/HIPAA_Statement.pdf.

[100] *Id.*

[101] 45 C.F.R. § 164.512.

[102] 45 C.F.R. § 164.512(b).

[103] *Id.*

[104] 45 C.F.R. § 164.512(d).

[105] 45 C.F.R. § 164.512(j).

[106] *Id.*

[107] LeFever, *supra* note 25, at 1056.

concerning for doctors and public health officials because "it reveals that a group of children who have historically received immunizations, and who have the best access to health care facilities, are no longer being protected." [108] This indicates that parents are choosing exemptions not due to religious beliefs, but "based on misinformation about safety."[109]

The rise in non-religious based exemptions leads to obvious questions: if these parents do not have religious objections, how are they legally exempting their children? In the states that provide for philosophical exemptions, parents' objections are covered. However, it is possible that in states where philosophical exemptions are not available, parents fabricate religious convictions in order to exempt their children. "This trend is dangerous because when parents deliberately refuse vaccination based on misinformation about safety, there may be very little that can be done to increase immunization rates until these concerns are disproved."[110]

Therefore, in terms of solutions to needless exemptions, the easiest exemption abuses to target and correct are those of convenience. "[S]tates should enact reasonable exemption processes that prevent opt-outs of convenience while respecting sincerely held individual rights and beliefs."[111] Ensuring that parents are not simply checking an exemption box because it is "easy" will preserve the exemption for those who have legitimate religious or philosophical reasons for claiming the exemptions.

In addition to eliminating exemptions of convenience, perhaps philosophical exemptions can be reduced as well. It seems that many parents claim philosophical exemptions based on fear of harm to their children, which may be founded on a lack of accurate information. Therefore, applications for philosophical exemptions should meet an "extraordinarily high standard of sincerity of belief against vaccination." [112] This may include an informed refusal stage and

---

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] Calandrillo, *supra* note 7, at 435.

[112] Coletti, *supra* note 58, at 1388.

discussion with healthcare providers.[113] However, even an informed refusal stage may not reassure some parents.

It is not surprising that many parents want to err on the side of safety and exempt their children whether or not vaccinations pose health hazards. Perhaps the most direct way to help stop exemption abuse is through the correction of misinformation about vaccinations and their safety. [114] The Centers for Disease Control and Prevention's National Immunization Program has already identified and refuted several common misconceptions regarding vaccination.[115]

In addition, public relations campaigns can educate parents regarding the risks of disease versus the risk associated with vaccines. The government must disseminate accurate data to the public in order to ensure that parents affirmatively desire to immunize their children instead of doing it reluctantly or under penalty of fines or imprisonment. Consequently, this may mean that more research needs to be completed to ensure that vaccinations are safe. Furthermore, funding should come from neutral sources that have no vested interest in the outcome of the research that would serve to undermine the results.

In sum, the best result will be reached by preserving an exemption for individual objections, but concurrently minimizing the use of exemptions through dissemination of accurate information and through the implementation of heightened standards for would-be exemptors. These solutions will allow parents to retain decisional privacy over healthcare choices, but will protect societal health by creating more informed parents and eliminating the reasons that some parents choose an exemption in the first place.

---

[113] *Id.* at 1388–89, 1392. *See also* Khalili & Caplan, *supra* note 6, at 474 ("Parents can make risk-based decisions without good information, but their decision making process can be improved with more complete information about vaccinations and the real dangers that exist."). Providing parents with more complete information could be handled in a variety of ways. Suggestions include requiring applicants for exemption to go through an "informed refusal" stage. Coletti, *supra* note 58, at 1341, 1388–89. Before conclusively refusing an exemption, parents would discuss the risks and benefits of immunization and exemption with health professionals. *Id.* at 1388. This would be especially helpful given the current incorrect beliefs that some parents hold. Studies suggest that "15% of adults believe vaccines are unnecessary to prevent disease and that 61% believe that childhood vaccines are at least somewhat unsafe." Khalili & Caplan, *supra* note 6, at 474. Perhaps an informed consent or refusal provision added to state exemption provisions would clarify misconceptions and result in some parents' acceptance of the desirability of vaccination.

[114] Novak, *supra* note 18, at 1127.

[115] *Id.*

X. CONCLUSORY REMARKS IN THE IIS DEBATE

There are viable options available for creation of laws that address public health concerns and plan for the potential of public health emergencies while preserving privacy to the fullest extent possible. The Centers for Disease Control and Prevention surveyed states to obtain information about state IIS legislation; the results not only highlight state by state legislation disparities, but indicate ways in which a national registry or individual state registries could be formulated to preserve optimal privacy.[116] The survey looked at the following relevant criteria: whether the state has a law mandating reporting to IIS; whether the state has a law addressing the sharing of immunization information; the type of consent required to participate in the state's IIS; whether provisions to opt-out or limit access were provided by the state; and whether notice was given of inclusion in the state's IIS.[117]

There are a number of ways these legislative categories can be structured in order to both preserve privacy and address public health concerns. A model IIS law might include a law mandating reporting and utilizing implied consent in order to address the concerns a public health emergency might pose. However, the model IIS legislation should also address the sharing of immunization information. This law should address penalties for violations and clearly define parties who may have access to confidential health information. Further, to counter-balance the mandated reporting and implied consent, model legislation should be structured to provide notice to parents of inclusion in the IIS. As a further privacy protection, legislation should provide provisions to opt-out of the IIS or to limit access. This type of legislation would ensure that public health is protected to the maximum extent possible, but still inform parents and allow those who are strongly opposed to opt-out.

---

[116] Nat'l IIS Survey, *supra* note 78.

[117] *Id.*